

The University of New Mexico Consent to Participate in Research:

Effect of immediate versus standard postpartum insertion of the Contraceptive implant on breastfeeding outcomes

03/11/2019

Key Information for Lacto-Rod: Effect of immediate versus standard postpartum insertion of the contraceptive implant on breastfeeding outcomes

You are being asked to participate in a research study because: you are a healthy female, 13 years or older, will deliver or delivered a baby by vaginal birth or cesarean section, intend to breastfeed, desire the etonogestrel implant as your method of birth control, agree to be randomized to early versus standard postpartum insertion, and are willing to complete all study-related procedures, visits, and questionnaires.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn how placing the Nexplanon implant (commonly called the implant) in the first 24 hours after birth affects how much women are breastfeeding 2 months later. Your participation in this research will last about six months. For detailed descriptions, refer to the Detailed Consent.

The purpose of this information is to gather information on the Nexplanon implant that is approved by the Food and Drug Administration (FDA) to use as birth control with a good record of safety in breastfeeding women. We usually wait to put in the implant until the 4th week after delivery or later. This research is to evaluate placing the Nexplanon implant in the first 24 hours after delivery which is not inconsistent with labeling indications.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There may or may not be direct benefit to you from being in this study. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The risks of being assigned to the immediate group are that it is possible that if placed immediately after delivery, the hormone part of the implant could decrease milk production. There is also the possible risk of decreased breast milk production by causes not associated to the implant insertion. Current but little data suggest there is no decreased breast milk with progestin-only methods. For a complete description of the risks, refer to the Detailed Consent/Appendix

You have the choice not to participate in the study and you can decide when to have an implant inserted at any time. For a complete description of alternate treatment/procedures, refer to the Detailed Consent/Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

As an employee, if you decide not to take part in this study, your choice will have no effect on your employment status.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Jamie Krashin, MD of the University of New Mexico Health Sciences Center, Department of OB/GYN. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is 505-205-4118, Monday-Friday 8am-430pm.

If you have any questions or concerns about your rights as a volunteer in this research, contact staff in the University of New Mexico Health Sciences (UNMHSC) Human Research Review Committee (HRRC) between the business hours of 8AM and 5PM, Mountain Standard Time (MST), Monday-Friday at 505-272-1129.

Detailed Consent

3/11/2019

Purpose and General Information

You are being asked to participate in a research study that is being done by Jamie Krashin, MD, who is the Principal Investigator and her associates because: you are a healthy female, 13 years or older, will deliver a baby, intend to breastfeed, desire the etonogestrel implant as your method of birth control, agree to be randomized to early versus standard postpartum insertion, and are willing to complete all study-related procedures, visits, and questionnaires.

This research is being done to evaluate how placing the Nexplanon implant (commonly called the implant) in the first 24 hours after birth affects how much women are breastfeeding 2 months later.

The Nexplanon implant is approved by the Food and Drug Administration (FDA) to use as birth control with a good record of safety in breastfeeding women.

We usually wait to put in the implant until the 4th week after delivery or later. However, many women cannot come back for their follow-up visit after the baby is born but desire long-acting birth control that will not be permanent so they can have another baby later. Putting in the implant before a woman leaves the hospital after she has her baby is one of the best methods for contraception available.

We want to make sure that this practice does not affect a woman's ability to successfully breastfeed her baby. Currently there are women who have chosen to have the implant inserted before leaving the hospital as their contraceptive method. However, because we don't have many studies on the effect of hormones on breastfeeding, this study seeks to determine if implant placement prior to leaving the hospital has any kind of bad effect on milk production compared to if the implant is placed 4-6 weeks after delivering a baby.

Up to 150 women will take part in this study at the University of New Mexico.

You will be excluded from the study if you are a pregnant women younger than 13, have a history of breast cancer, history of undiagnosed vaginal bleeding, head trauma that affected your pituitary function, prolactin insufficiency, previous complete failure to lactate, contraindication to lactation or any disease transmittable by breast milk, liver dysfunction, taking drugs that inhibit lactation, sensitivity to the components in the etonogestrel implant. If the participant have any contraindication to use the implant this will be evaluated on individual based and accordingly to the United State Medical Eligibility Criteria (US MEC).

A limited number of implants will be available **for women without insurance who cannot afford the out-of-pocket cost**. The acquisition of the implant will depend on availability while supply last.

What will happen if I decide to participate?

If you agree to participate, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen:

You will be assigned by chance (like a flip of a coin) to receive either early insertion of the implant or standard insertion of the implant, so you will have an equal chance of receiving either procedure. This means that the implant will be put in the first 24 hours (early insertion) and the other group will have the implant put in at a clinic visit in 4-6 weeks (standard insertion).

You will have a physical examination, past medical history and your medical history related to your delivery and your baby will be reviewed. Information to be collected from your medical records includes your medical record number, information about how many times you have been pregnant and how many babies you have had as well as information about your delivery and about your infant at the time of delivery.

We will collect contact information from you including telephone number, address, email, and two alternative contacts who can always contact you. In addition, text message will be sent to you with links to the study questionnaires and reminder messages. This information will be used to contact you for your follow up visits. We will use the alternative contact numbers in case we are not able to reach you at your primary contact numbers. After your delivery, we will collect data on your contraceptive choices. While you are in the hospital, we will collect information about you regarding your medical and pregnancy history. If you are in the "early insertion" group, a physician will put in your implant in the

first 24 hours after delivery. If you are in the “standard insertion” group, you will have your implant put in at a clinic visit 4-6 weeks after your baby’s birth.

As part of your participation in this study, we will contact you daily until your milk has come in. We will prepare you for the signs you will see when your milk comes in, and ask that you record the time this happens.

We will also give you a diary to record the information needed for the study follow-up period.

Then, we will call you at 2 weeks after your baby’s birth, and at 4, 8, 12, and 24 weeks to ask about your breastfeeding status, any supplements you feed the baby, bleeding patterns, return to sexual intercourse, and what kind of contraception you are using.

If you did not received the implant in the first 24 hours after delivery, you will need to come for a clinic visit 4-6 weeks after your baby’s birth (if you are in the standard insertion group) to have the implant inserted.

We will contact you at weeks 2, 4, 8, 12 and 24 weeks after your baby’s birth for a short interview or questionnaires by phone or a link will be sent through text message or email.

At 3 & 6 months after your baby’s birth, you will be asked to either mail in your diary or submit it through a link sent through text message or email.

For your convenience, we have two options to complete the questionnaires of the study. The first option is by phone call done by the research team or electronically through our secure database called RedCap.

How long will I be in this study?

Participation in this study will take a total of 9-12 hours or less depending on how much time will take you to answer the questionnaire. The total length of the study is 24 weeks that is the same as six months.

What are the risks or side effects of being in this study?

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

The risks of being assigned to the immediate group are that it is possible that if placed immediately after delivery, the hormone part of the implant could decrease milk production.

There is also the possible risk of decreased breast milk production by causes not associated to the implant insertion.

Current but little data suggest there is no decreased breast milk with progestin-only methods. For more information about the risks and side effects, ask the investigator.

If your responses during this study are concerning for postpartum depression, you may receive a referral to counseling treatment.

How will my information be kept confidential?

Your name and other identifying information that are in paper forms will be maintained in locked files, available only to authorized members of the research team, for the duration of the study. For any information entered into a computer, the only identifier will be a unique study identification (ID) number. Any personal identifying information and any record linking that information to study ID numbers will be destroyed when the study is completed. Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by the Sponsor, federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research. There may be times when we are required by law to share your information. However, your name will not be used in any published reports about this study.

What are the benefits to being in this study?

There may or may not be direct benefit to you from being in this study. However, your participation will help in the treatment of future patients with understanding of how an implant affects breastfeeding.

What other choices do I have if I do not want to be in this study?

Taking part in this study is voluntary so you can choose not to participate, and this will not affect your clinical care or treatment. You have the choice not to participate in the study and you can decide when to have an implant inserted at any time. It is up to you to decide whether or not to take part in this study. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What happens if you get hurt or sick during the study?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call 505-272-2111 (UNM hospital operator) and ask for the Family Planning Fellow on call or the study coordinator at 505-205-4118. UNM Health Sciences Center (HSC) will provide you with emergency treatment, at your cost.

No commitment is made by the UNM HSC to provide free medical care or money for injuries to participants in this study. You are responsible for the cost of the implant and its insertion.

It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while

taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

In the event that the patient has an injury or illness that is caused by participation in this study, patients will be verbally reminded of the following during the consent process: reimbursement for all related costs of care will be sought from the patient's insurer, managed care plan, or other benefits program. If they do not have insurance, they may be responsible for these costs. Patients will also be responsible for any associated co-payments or deductibles required by their insurance.

I understand that I will have to pay for the usual charges of routine women care, annual visits or to remove the implant.

It is important for you to tell the investigator immediately if you have been injured or become sick because of taking part in this study. If you have any questions about these issues, or believe that you have been treated carelessly in the study, please contact the Human Research Review Committee (HRRC) at the (505) 272-1129 for more information.

Will I be paid for taking part in this study?

In return for your time and the inconvenience of participating in this study, you will be paid a total of \$40 to participate in this research study. This incentive will be divided in two gift cards of \$20. The first gift card will be given at the time of implant insertion. The second gift card of \$20 will be given after completing the 6-month follow up.

How will I know if you learn something new that may change my mind about participating?

You will be informed of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating.

Can I stop being in the study once I begin?

Yes. You can withdraw from this study at any time without affecting your access to care. The investigators have the right to end your participation in this study if they determine that you no longer qualify to take part, if you do not follow study procedures, or if it is in your best interest or the study's best interest to stop your participation.

Whom can I call with questions or complaints about this study?

If you have any questions, concerns or complaints at any time about the research study, Dr. Jamie Krashin or her associates will be glad to answer them at 505-205-4118, Monday-Friday 8am-430pm. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNM HSC and the community who provide independent oversight of safety and ethical issues related to research involving human participants.

A description of this study clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

What are my rights as a research participant?

If you have questions regarding your rights as a research participant, you may call the Human Research Protections Office (HRPO) at (505) 272-1129 or visit the HRPO website at <http://hsc.unm.edu/som/research/hrrc/>.

HIPAA Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)

As part of this study, we will be collecting health information about you but this information will not be share with people outside of the authorized study members. This information is “protected” because it is identifiable or “linked” to you.

Protected Health Information (PHI)

By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include result of physical exams, medical history, obstetrical and gynecological history and infant history at birth. You are legally entitled to review mental health information collected in the study.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization

Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a letter notifying them of your withdrawal to:

Jamie Krashin, MD
Department of Obstetrics and Gynecology
MSC 10 5580, 1 University of New Mexico
Albuquerque, New Mexico 87131-0001

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign

If you choose not to sign this consent form and authorization for the use and disclosure of your personal health information, you will not be allowed to take part in the research study.

Consent and Authorization

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you) and you are signing freely and voluntarily. By signing this Consent Form, you are not waiving any of your legal rights as a research participant.

I have had an opportunity to ask questions and all questions have been answered to my satisfaction. By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. A copy of this Consent Form will be provided to me.

The research team member explained to me the communication modality of text message. I understand the text messages will be used to send me links to the study questionnaires and to send me reminders about participation in the study and

____ I agree to receive text message to the following

Phone number: _____ Carrier: _____

____ I do not want to receive text message.

Name of Adult Participant (print)

_____/_____
Signature of Adult Participant Date

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information in this consent form and freely consents to participate.

Name of Research Team Member

_____/_____
Signature of Research Team Member Date

Parental Consent

I have read and took in consideration of all of the above, I give my consent for my child to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to allow my child to take part in this study.

Name of Parent or Legal Guardian

_____/_____
Signature of Parent(s) or Legal Guardian Date

Child Assent (13-17 years old)

You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you).

Name of Child Participant

Signature of Child Participant

/

Date